Peripheral stents: design investigation through computational tools

Michele Conti

Supervisor(s): F. Auricchio (University of Pavia), B. Verhegghe and M. De Beule (Ghent University)

I. Introduction

Cardiovascular disease (CVD) has a huge social impact in Western countries (49% of all deaths in 2005 [1]). CVD is often related to atherosclerosis, a degeneration of the vessel wall, leading to a stenosis, i.e. the narrowing of the vessel lumen, which can have dramatic effects as a stroke or a heart attack. Currently, minimally invasive treatment of stenoses by means of cylindrical metal structures (stents) has become common and widely-used for atherosclerotic coronaries and the trend is to apply this technique for atherosclerotic peripheral vessels such as the Superficial Femoral Artery (SFA) or the Carotid Artery (CA). Thanks to the peculiar features of Nitinol, a shape memory alloy, peripheral stents accomplish both technical and biomechanical requirements (i.e. flexibility, kink resistance, low delivery profile etc.) but, unfortunately, peripheral stenting still suffers several limitations especially due to stent fracture, in-stent restenosis, stent migration and/or malapposition due to the tortuous anatomy. Consequently, there is a significant need to relate the peripheral stenting performance to the features of device design as recently highlighted by several clinical experts [2]. The aim of this study is to investigate the impact of stent design on peripheral stenting performance by Finite Element Analysis (FEA); in particular, the present study evaluates the impact of stent configuration, i.e. straight vs tapered [1], on the lumen gain and the vessel straightening (comparing the pre and post stenting tortuosity).

II. Material and Methods

Realistic simulations of CA Stenting (CAS) have to face with several issues ranging from the accurate modeling of both the carotid artery and the stent design to the loading on stent due to the vessel kinematics. Moreover it is necessary to take into account also the stent manufacturing process which can be resumed in three steps:(i) laser-cutting of a small Nitinol tube; (ii) expansion of the surface treated laser-cut configuration (shape setting) by the insertion of a punch; (iii) heat treatment (annealing) in order to set the superelastic properties and the new expanded geometry. This study proposes a software framework, coupling pyFormex (http://pyformex.berlios.de/) as pre and post-processing software and Abaqus (version 6.8 - Abaqus Inc., Providence, RI, USA) as finite element solver, allowing to analyze numerically a Nitinol stent design from the laser-cutting stage to its deployment in carotid artery model based on patient specific data. Firstly, the finite element model of a commercially

M. Conti is attending the Joint-PhD programme between Structural Mechanics Department, Universitá degli Studi di Pavia, Pavia, Italy and Institute Biomedical Technology (IBiTech), Ghent University, Gent, Belgium. E-mail: Michele.Conti@UGent.be .

[1] The distal diameter is smaller than the proximal one to set a conical shape accounting for the diameter difference between the vessel branches of the carotid bifurcation.

available stent design in laser-cut configuration is created; the model is based on 3D reconstruction from micro-CT scan. Then, a FEA to simulate the shape setting is performed to get the free expanded stent configuration. Subsequently, DICOM images of a CTA (Computed Tomography Angiography) are processed to create the finite element model of the stenotic vessel. Finally the stress free expanded stent and the vessel model are combined with the catheter model to perform a FEA of the CAS in order to evaluate the impact of stenting on vessel deformation for a given design.

III. RESULTS

The results of both the shape setting and CAS simulations are illustrated in figure III. During the release, the stent expands in order to recover its original shape by exploiting the Nitinol superelastic effect enlarging the narrowed vessel.

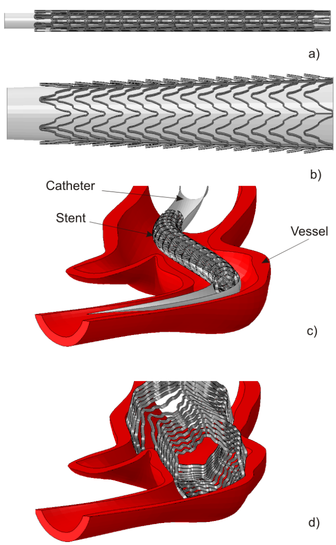

Figure 1. Tapered stent: a) initial laser-cut configuration; b) configuration after shape setting; c) stent within the delivery system: a) fully deployed stent within the carotid artery.

Table 1 reports the lumen gain and vessel straightening for a straight and tapered stent configuration. The results are obtained elaborating and comparing the pre and post vessel geometry. Speculating on these preliminary results, it is possible to state that for the investigated anatomy is preferable to use a stent in a straight configuration which provides a major lumen gain and has a slightly minor impact on the vessel tortousity compared to the tapered configuration.

Table 1. Lumen gain and vessel straightening.

Configuration	Straight	Tapered
Lumen Gain	57.1%	46.5%
Vessel Straightening	-51.6%	-54.9%

IV. CONCLUSIONS AND FURTHER DEVELOPMENTS

Accurate numerical models of prosthesis implants can play an important role to design and evaluate medical devices and to reduce their time to market. The present study investigates peripheral stenting by means of FEA using a patient specific artery model representing consequently a base for both CAS procedure planning and development of novel stent designs. The present investigation framework can be exploited to compare different designsand also can be extended to other peripheral districts such as SFA; further investigation can include experimental validation and a more accurate constitutive modeling of the vessel tissue.

ACKNOWLEDGMENTS

The authors would like to acknowledge Eng. G. De Santis and Eng. D. Van Loo.

REFERENCES

[1] Petersen S, Peto V, Rayner M, Leal J, Luengo-Fernandez R and Gray A. 2005. European cardiovascular disease statistics. BHF London
[2] Bosiers M, de Donato G, Deloose K, Verbist J, Peeters P, Castriota F, Cremonesi A and Setacci C. 2007. Does Free Cell Area Influence the Outcome in Carotid Artery Stenting?. Eur J Vasc Endovasc Surg. 33: 135-141.